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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/593,691	09/15/2000	George Wu	PT1443001	6763

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EXAMINER	
STILLER, KARL J	

ART UNIT	PAPER NUMBER
1617	4

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Please find below and/or attached an Office communication concerning this application or proceeding.

4

Office Action Summary	Application No. 09/593,691	Applicant(s) WU ET AL.	
	Examiner Karl Stiller	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 38-82 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 38-82 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/558,472 .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application is a continuation of 08/558,472, filed November 16, 1995.

Specification Objections

The application filed June 15, 2000 as a continuation of application 08/558,472 is objected to under 37 CFR 1.53 because it introduces new matter into the disclosure. 37 CFR 1.53 states that no new matter may be introduced into an application after its filing date. The added material which is not supported by the original disclosure is as follows: the inclusion of bicarbonate in Claims 45, 56, 67, 79, and Claims that depend from these Claims. Bicarbonate or incorporation by reference of a bicarbonate containing composition is not disclosed in the specification as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-48, 56-59, 67-70, and 79-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant application is a continuation of 08/558,472 (now US Patent

6,083,935), filed November 16, 1995 and claims priority of foreign application, CA 2,155,190 A1, filed August 11, 1995. Neither priority document provides for the employment of bicarbonate in the products or methods therein either expressly or by incorporation by reference.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 recites the limitation "the" in the third line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

Since the employment of bicarbonate is not disclosed in the priority documents and is considered new matter, it is not covered under the following obvious type double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 38-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-7 of Wu et al. (US 6,083,935). Although the conflicting claims are not identical, they are not patentably distinct from each other because scope of the patent and claimed invention overlap.

Wu et al. teaches a composition comprising the recited percentage (w/v) range of the amino sugar, N-acetylglucosamine, the recited mEquiv/L range of sodium, from 0.6 to 3.24 mEquiv/L of calcium, the recited mEquiv/L range of chloride, the recited mEquiv/L range of magnesium, the recited mEquiv/L range of lactate, malate, acetate, succinate, or combinations thereof, and the recited pH range of the final composition (see Claims 1-3, column 6, line 44 through column 7, line 6). Wu et al. also teaches the interchangability of amino sugars related to N-acetylglucosamine in the claimed composition, specifically polymers or oligimers comprised of between 2 and 12 carbohydrate units of N-acetylglucosamine, glucosamine, N-acetylgalactosamine, galactosamine, N-acetylmannosamine, mannosamine, or combinations thereof (see column 3, lines 21-39, column 4, lines 25-29, lines 35-47, column 4, line 65 through column 5, line 12).

Wu et al. also teaches a method of performing peritoneal dialysis, comprising the introduction of the disclosed peritoneal dialysis composition into the peritoneal cavity of a patient (see Claims 1-4, column 6, line 44 through column 7, line 10).

Wu et al. also teaches a method of treating a patient suffering from renal failure, comprising the introduction of the disclosed peritoneal dialysis composition into the peritoneal cavity of a patient (see Claims 1-3, and 5, column 6, line 44 through column 7, line 6, lines 11-14).

Wu et al. also teaches a method of reducing at least one complication associated with peritoneal dialysis, comprising the introduction of the disclosed peritoneal dialysis composition into the peritoneal cavity of a patient (see Claims 1-3, and 6-7, column 6, line 44 through column 7, line 6, column 8, lines 1-12).

The reference does not particularly disclose a range of 0.6-5.0 mEquiv/L for calcium in the product or methods herein.

It would have been obvious at the time the invention was made to modify the invention of Wu et al. (US 6,083,935) by employing the recited range of 0.6-5.0 mEquiv/L for calcium since it is similar to the prior art (0.6 to 3.24 mEquiv/L) and the optimization of a dosage regimen for active agents is considered within the skill of the artisan as optimization of a result effective parameter. See *In re Boesch* 205 USPQ 215.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 38-44, 49-55, 60-66, and 71-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seyffart et al. (US 4,879,280) and Breborowicz et al. (EP 0 555 087 A1) in view of "Textbook of Biochemistry".

Seyffart et al. discloses a composition having an osmolarity from 395 to 510 mOsm/L comprising an osmotically active oligosaccharide with low bioavailability via the peritoneum, 134 mEq/L of the electrolyte, sodium, 0.875 mEq/L of the electrolyte, calcium, 105.5 mEq/L of the electrolyte, chloride, 0.25 mEq/L of the electrolyte, magnesium, and 35 mEq/L of the electrolyte, lactate (see column 3, lines 6-12, column 5, lines 15-32, and column 6, lines 29-39). Seyffart et al. also discloses a method of performing peritoneal dialysis comprising the introduction of the disclosed composition comprising introducing the composition into the peritoneal cavity of a patient (see column 5, lines 7-14). Seyffart et al. further discloses that compositions comprising osmotically active oligosaccharides with low bioavailability via the peritoneum are useful to treat patients suffering from renal failure (see column 1, lines 15-19). Seyffart et al.

further discloses that compositions comprising osmotically active oligosaccharides with low bioavailability via the peritoneum are useful in a method to reduce at least complication associated with peritoneal dialysis, such as peritonitis (see column 2, lines 57-59).

Breborowicz et al. discloses a peritoneal dialysis composition with a pH between 5.0 and 7.4, comprising degradation products of hyaluronic acid, 116-140 mEq/L of the electrolyte, sodium, 0-6 mEq/L of the electrolyte, calcium, 100-144 mEq/L of the electrolyte, chloride, and 30-45 mEq/L of the electrolyte, lactate (see column 6, lines 6-15, lines 38-41). Breborowicz et al. also discloses that peritoneal dialysis compositions comprising degradation products of hyaluronic acid are useful in a method to reduce at least one complication associated with peritoneal dialysis, such as morphological and functional deterioration of the peritoneal membrane (see column 3, lines 4-11, column 6, lines 38-41).

The primary references, collectively, do not particularly disclose a composition comprising an amount of at least one amino sugar, specifically identified as a monomer or as an oligomer of 2 to 12 carbohydrate units, sufficient to create an osmotic pressure to effect the removal of water by diffusion from a patient or at a concentration of up to about 5.0%(w/v), with or without at least one electrolyte in an amount useful herein (see Claim 44). Additionally, the primary references, collectively, do not particularly disclose a method of performing peritoneal dialysis, a method of treating a patient suffering from renal failure, or a method of reducing at least one complication associated with peritoneal dialysis, comprising the employment of the same composition.

"Textbook of Biochemistry" discloses that N-acetylglucosamine is a degradation product of hyaluronic acid (see p. 1324-1325, inclusive).

It would have been obvious at the time the invention was made to modify the references by employing at least one amino sugar, such as N-acetylglucosamine, in a peritoneal dialysis composition in the amounts recited herein with or without at least one electrolyte in an amount useful herein. It would also have been obvious at the time the invention was made to employ the same composition in a method of performing peritoneal dialysis, a method of treating a patient suffering from renal failure, or a method of reducing at least one complication associated with peritoneal dialysis.

One of ordinary skill would have been motivated to employ at least one amino sugar, such as N-acetylglucosamine, in the peritoneal dialysis composition herein since Breborowicz et al. discloses a peritoneal dialysis composition comprising degradation products of hyaluronic acid and "Textbook of Biochemistry" discloses that N-acetylglucosamine is a known degradation product of hyaluronic acid. Hyaluronic acid degradation products, such as N-acetylglucosamine are expected to be useful in peritoneal dialysis compositions. The employment of at least one amino sugar, such as N-acetylglucosamine, in a peritoneal dialysis composition with or without at least one electrolyte is considered *prima facie* obvious since hyaluronic acid degradation products and electrolytes are known to be useful individually in peritoneal dialysis compositions. Their combination into a single composition useful for the very same purpose, peritoneal dialysis, is clearly motivated by the prior art. See *In re Kerkhoven* 205 USPQ 1069. Additionally, one of ordinary skill would have been motivated to employ actives in the

amounts recited herein since the optimization of a dosage regimen for active agents or amounts of an active to be administered is considered within the skill of the artisan as optimization of a result effective parameter. See *In re Boesch* 205 USPQ 215.

Further, one of ordinary skill would have been motivated to employ the same peritoneal dialysis composition in a method to perform peritoneal dialysis, a method to treat a patient suffering from renal failure, or in a method to reduce at least one complication associated with peritoneal dialysis since Breborowicz et al. discloses that peritoneal dialysis compositions which comprise hyaluronic acid degradation products, such as N-acetylglucosamine, are useful in these same methods.

Since the employment of bicarbonate in the instant composition and methods was not disclosed in the priority document, US 08/558,472 and CA 2,155,910 A1, it is considered new matter. Therefore, the priority date of claims directed to the employment of this new matter is considered to be the date of filing of the National Stage of the PCT application, June 15, 2000. Thus, Kubo et al. (JP11-71273-A) is considered prior art.

Claims 45-48, 56-59, 67-70, and 79-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kubo et al. (JP11-71273-A).

Kubo et al. discloses a peritoneal dialysis composition with a pH between 6.0 and 7.5 and an osmotic pressure from 280 to 600 mOsm/kg, comprising 0-6.5g/dl (0% to 65% w/v) of the amino sugar, N-acetyl-D-glucosamine, 50-150mEq/L sodium, 0-5mEq/L calcium, 30-110mEq/L chloride, 0-3mEq/L magnesium, 0-50mEq/L lactate, 0-50mEq/L

acetate, and 0-50mEq/L bicarbonate (see p. 9, line 1 through p. 10, line 17). Kubo et al. also discloses a method of performing peritoneal dialysis comprising the introduction of their peritoneal dialysis composition into the peritoneal cavity of a patient (see p. 13, line 17 through p. 14, line 39). Kubo et al. also discloses the usefulness of employing the disclosed peritoneal dialysis composition in a method of treating a patient suffering from renal failure (see p. 11, lines 38-44). Kubo et al. also discloses the usefulness of employing the disclosed peritoneal dialysis composition in a method of reducing at least one complication associated with peritoneal dialysis, for example, the administration of an amino sugar herein is taught to solve the problem of decomposition product production formed by heat sterilization of peritoneal dialysis compositions commonly used in the art which comprise glucose; by employing an amino sugar in place of glucose, the peritoneal dialysis composition herein is taught to avoid the problem of weight gain and complications associated with administering a glucose containing product to a diabetic patient; the disclosed peritoneal dialysis composition is taught to be less likely to damage the peritoneum, and can therefore be employed in a method of dialyzing a patient over an extended period of time; the disclosed peritoneal dialysis composition is taught to offer a more persistent dialyzation action since the amino sugar is less readily absorbed through the peritoneum than is glucose, which results in a lengthened usable exchange time, the reduction in the number of dialysis injections needed, and an improvement in a patients quality of life (see p. 6, line 8 through p. 8, line 15, p. 11, lines 24-44).

The reference does not particularly disclose a peritoneal dialysis composition comprising at least one amino sugar at a concentration of up to about 5.0% (w/v) or chloride in the range of about 100-145mEq/L or the employment of the same in the methods herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the reference by employing a concentration of up to about 5.0% (w/v) of at least one amino sugar, a concentration of about 100-145mEq/L in a peritoneal dialysis composition. It would also have been obvious to employ the same peritoneal dialysis composition in the methods herein.

One of ordinary skill in the art would have been motivated to modify the amino sugar concentration and the chloride concentration of the peritoneal dialysis composition since the reference teaches the amino sugar concentration from 0-6.5g/dl (0% to 65% w/v), which encompasses the range recited herein. The reference also teaches chloride from 30 to 110mEq/L to adjust the osmolarity (see p. 9, line 1 through p. 10, line 17). Absent evidence to the contrary, it is considered within the skill of the artisan to adjust the chloride amount up to about 145mEq/L in order to obtain a peritoneal dialysis composition with the disclosed osmolarity from 280mOsm/kg to 600mOsm/kg. One would also have been motivated to employ the same peritoneal dialysis composition in a method of performing peritoneal dialysis, treating a patient suffering from renal failure, or reducing at least one complication associated with peritoneal dialysis since the usefulness of peritoneal dialysis compositions

encompassed by Kubo et al. in the same methods is disclosed (see p. 6, line 8 through p. 8, line 15, p. 11, lines 24-44, p. 13, line 17 through p. 14, line 39).

Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited reference.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl Stiller whose telephone number is 703-306-3219. The examiner can normally be reached Monday through Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached at 703-308-4612. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Stiller: ks
January 2, 2002

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